

**Notice of Allowability**

Application No.

10/056,583

Applicant(s)

STROMINGER ET AL.

Examiner

Art Unit

Bridget E. Bunner

1647

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of 14 December 2004.
2. ☒ The allowed claim(s) is/are 28-29, 32, and 61 (renumbered as claims 1-4, respectively).
3. ☒ The drawings filed on 24 January 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 3/25/03
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### **DETAILED ACTION**

Applicant's election with traverse of Group 20, claims 28-32 and 61, drawn to a composition comprising a synthetic peptide of SEQ ID NO: 93 in the reply filed on 14 December 2004 is acknowledged. The traversal is on the ground(s) that the compositions of claim 28 are structurally and functionally related peptides that were obtained by design and produced by organic synthetic methods. Applicant argues that the sequences have functional residues that differ at each of only a few positions, however the differences involve functionally similar amino acids. This is found to be persuasive. Therefore, the restriction election requirement for Groups 4-26 as set forth in the Restriction of 14 October 2004 is withdrawn. The synthetic peptides sequences recited in claim 28 are rejoined.

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Sonia Guterman on 05 April 2005.

The application has been amended as follows:

Please cancel claims 30 and 49-60.

*Informal Examiner's Amendment*

2. At page 2, line 36 of the specification, the Examiner has inserted a paragraph break before the phrase "FIG. 5A is a bar graph...".
3. At pg 15, line 29 of the specification, the Examiner has deleted the embedded hyperlink.
4. At pg 15, line 28 of the specification, the Examiner has inserted ")" after the phrase "...Rockville, MD".
5. Please delete the title of the invention of the instant application and insert "SYNTHETIC PEPTIDES FOR DEMYLINATING CONDITIONS".
6. The following is an examiner's statement of reasons for allowance:

The thirteen short synthetic peptides recited in the claims are novel and nonobvious. The claims of the instant application are free of prior art because these short sequences have not been disclosed or studied in the prior art. The specification meets 35 U.S.C. 112, first paragraph, requirements because it contains an adequate written description of the invention that enables one of ordinary skill in the art to make and use the invention (see pages 25-29 of the specification and Figures 1-8). For example, the specification of the instant application teaches that the synthetic peptides of SEQ ID NOs: 64-66, 84, 86, 88-91, 93, and 95-97 inhibit myelin basic protein (MBP) 85-99 from binding to HLA-DR2 molecules and also inhibit the proliferation of HLA-DR2 restricted MBP 84-102-specific T cell transfectant 8073 in a concentration dependent manner. The synthetic peptides having a phenylalanine, valine, or tyrosine at the P-1 position pocket (as it relates to the residue at position 5 of MBP 85-99) are

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effective inhibitors. Similarly, the synthetic peptides having a phenylalanine or tyrosine at the P-4 position are effective inhibitors. The specification also sets forth the best mode to carry out the invention. The claims also meet 35 U.S.C. 112, second paragraph, requirements because the claims point out and distinctly claim the invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

### ***Conclusion***

The Examiner's amendment to the claims served to clarify the claims. Applicant has the right to file divisional or continuation applications to protect the inventions in the cancelled claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881.

The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BEB  
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06 April 2005

*Elizabeth C. Kemmerer*

**ELIZABETH KEMMERER  
PRIMARY EXAMINER**